REMARKS

Claims 37-127 and 129-168 are pending in the application. Claims 42-48 and new claims 158-168 are elected. Claim 42 has been amended. Support for the amendment to claim 42 is found on page 221. Claims 158 through 168 are newly added and contain elected subject matter. No new matter has been added.

Applicants request allowance of all claims if the generic claims are held allowable.

Applicants submit that the use of uncapped poly(lactide/glycolide) polymer and the use of a blend of uncapped and end-capped poly(lactide/glycolide) polymer in a microcapsule formulation is novel.

Respectfully submitted,

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By 

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Versions with markings to show changes made.

IN THE CLAIMS:

Please amend the claims as follows;

42. (Twice Amended) A process for preparing controlled release compositions characterized by burst-free, sustained, programmable release of biologically active agents, comprising: dissolving biodegradable poly(lactide/glycolide), in uncapped form and biodegradable poly(lactide/glycolide) in end-capped form in methylene chloride, and dissolving a biologically active agent or active core in water; adding the aqeous layer to the polymer solution and emulsifying to provide an [innter] inner water-in-oil (w/o) emulsion; stabilizing the w/o emulsion in a solvent-saturatured aqueous phase containing [a] an oil-in-water (o/w) emulsifier; adding said w/o emulsion to an external aqueous layer containing oil-in-water emulsifier to form a ternary emulsion; and stirring the resulting water-in-oil-in-water (w/o/w) emulsion for sufficient time to remove said solvent, and rinsing hardened microcapsules with water and lyophilizing said hardened microcapsules.

Please add the following new claims

---158. (New) The process of claim 42, wherein the biologically active agent is a polypeptide.

159 (New) The process of claim 158, wherein said polypeptide is any of the vaccine agents against enterotoxigenic *E. coli* selected from the group consisting of CFA/I, CFA/II, CS1, CS3, CS6, and CS17, ETEC-related enterotoxins, and combinations thereof.

160. (New) The process of claim 159, wherein said polypeptide is CFA/I.

161. (New) The process of claim 160, wherein said CFA/I polypeptide is synthetic and is selected from the group of synthetic peptides containing the CFA/I pilus protein T-cell epitopes (Starting Sequence # given)

4(Asn-Ile-Thr-Val-Thr-Ala-Ser-Val-Asp-Pro),

8(Thr-Ala-Ser-Val-Asp-Pro-Val-Ile-Asp-Leu),

12(Asp-Pro-Val-Ile-Asp-Leu-Leu-Gln-Ala-Asp),

15(Ile-Asp-Leu-Leu-Gln-Ala-Asp-Gly-Asn-Ala),

20(Ala-Asp-Gly-Asn-Ala-Leu-Pro-Ser-Ala-Val),

26(Pro-Ser-Ala-Val-Lys-Leu-Ala-Tyr-Ser-Pro),

72(Leu-Asn-Ser-Thr-Val-Gln-Met-Pro-Ile-Ser),

78(Met-Pro-Ile-Ser-Val-Ser-Trp-Gly-Gly-Gln),

87(Gln-Val-Leu-Ser-Thr-Thr-Ala-Lys-Glu-Phe),

126(Ala-Gly-Thr-Ala-Pro-Thr-Ala-Gly-Asn-Tyr), and

133(Gly-Asn-Tyr-Ser-Gly-Val-Val-Ser-Leu-Val), and mixtures thereof;

synthetic peptides containing CFA/I pilus protein B-cell (antibody) epitopes (starting sequence given)

3(Lys-Ana-Ile-Thr-Val-Thr-Ala-Ser-Val),

11(Val-Asp-Pro-Val-Ile-Asp-Leu-Leu-Gln-Ala-Asp),

22(Gly-Asn-Ala-Leu-Pro-Ser-Ala-Val),

32(Ala-Tyr-Ser-Pro-Ala-Ser-Lys-Thr-Phe-Lys-Thr-Phe-Glu-Ser-Tyr-Arg-Val),

32(Ala-Tyr-Ser-Pro-Ala-Ser-Lys-Thr-Phe),

38(Lys-Thr-Phe-Glu-Ser-Tyr-Arg-Val),

66(Pro-Gln-Leu-Thr-Asp-Val-Leu-Asn-Ser),

93(Ala-Lys-Glu-Phe-Glu-Ala-Ala-Ala),

124(Lys-Thr-Ala-Gly-Thr-Ala-Pro-Thr),

127(Gly-Thr-Ala-Pro-Thr-Ala-Gly-Asn-Tyr-Ser),

124(Lys-Thr-Ala-Gly-Thr-Ala-Pro-Thr-Ala-Gly-Asn-Thr-Ser), and mixtures thereof; and

synthetic peptides containing CFA/I pilus protein T-cell and B-cell (antibody) epitopes (starting sequence # given)

3(Lys-Asn-Ile-Thr-Val-Thr-Ala-Ser-Val-Asp-Pro),
8(Thr-Ala-Ser-Val-Asp-Pro-Val-Ile-Asp-Leu-Leu-Gln-Ala-Asp),
11(Val-Asp-Pro-Val-Ile-Asp-Leu-Leu-Gln-Ala-Asp),
20(Ala-Asp-Gly-Asn-Ala-Leu-Pro-Ser-Ala-Val),
124(Lys-Thr-Ala-Gly-Thr-Ala-Pro-Thr-Ala-Gly-Asn-Tyr-Ser), and
126(Ala-Gly-Thr-Ala-Pro-Thr-Ala-Gly-Asn-Tyr-Ser), and mixtures thereof.

162. (New) The process of claim 42, wherein release profiles of variable rates and duration are achieved by blending said uncapped and said end-capped forms of poly(lactide/glycolide) polymer in different ratios within the same microcapsule.

163. (New) The process of claim 42, wherein when the ratio of uncapped polymer to end-capped polymer is increased, the release rate of the active ingredient increases.

164. (New) The process of claim 42, wherein the uncapped polymer and end-capped polymer is present in ratios ranging from 100/0 to 1/99, respectively.

165. (New) The process of claim 42, wherein the uncapped polymer and end-capped polymer is present in ratios ranging from 90/10 to 40/60.

166. (New) The process of claim 42, wherein the relative ratio between the lactide and glycolide (L/G) component is within the range of 40/60 to 0/100.

167. (New) The process of claim 42, wherein the relative ratio between the lactide and glycolide (L/G) component is within the range of 90/10 to 40/60.

168. (New)The process of claim 42, wherein the relative ratio between the lactide and glycolide (L/G) component is within the range of 48/52 to 52/48.---.